

**Selected Recommendations of the  
OPTN/UNOS Thoracic Organ Transplantation Committee to the  
Board of Directors  
June 22-23, 2009  
Richmond, Virginia**

**Summary**

**I. Action Items for Board Consideration**

- The Committee asks the Board to approve the addition of “current bilirubin” and “increase in bilirubin” as factors to the waitlist survival model in the lung allocation score. Analyses revealed the association between high bilirubin levels and waitlist mortality. (Modification to Policy 3.7.6.1 (Candidates Age 12 and Older) (Item 1, page 3)
- The Committee asks the Board to approve the Programming Diagnosis Changes in the Lung Waitlist<sup>SM</sup> Web Pages. (Item 2, page 6)
- The Committee asks the Board to approve programming modifications that will allow centers to enter three numbers to the right of the decimal point. (Item 3, page 7)
- The Committee asks the Board to approve changes to inotrope programming that will make it consistent with Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status). (Item 3, page 7)

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**Maryl R. Johnson, MD, Chair  
Mark L. Barr, MD, Vice-Chair**

This report presents selected recommendations of the Thoracic Organ Transplantation Committee on issues that were discussed at the November 21, 2008 and March 27, 2009 meetings.

**1. Modifications to Policy 3.7.6.1 (Candidates Age 12 and Older): Adding Current Bilirubin and Change in Bilirubin to the Lung Allocation Score (LAS)**

Starting in late 2006, the Committee began its discussion on the impact of bilirubin on the LAS. In the ensuing years, the Committee analyzed the statistical and clinical impact of bilirubin on waiting list mortality and survival after transplant<sup>1</sup>.

From June 30, 2008 through September 24, 2008, the Committee submitted for public comment a proposal to add change in bilirubin (an increase of 50% or higher in a six-month period) to the LAS<sup>2</sup>. The Lung Subcommittee convened on October 16, 2008 to review comments on the proposal. The public as well as the Committees and Regions submitted favorable comments on the proposal. The Subcommittee, however, upon reviewing again the statistical evidence supporting the addition of change in bilirubin to the LAS, reconsidered the policy proposal. Specifically, the Subcommittee questioned the inclusion of the creatinine variable in some of the data published in the June 2008 public comment proposal<sup>3</sup>. (This earlier proposal was based primarily on quantitative data that included creatinine as well as bilirubin; however, the Committee did not propose that creatinine be incorporated into the waiting list component of the LAS.) The Subcommittee asserted that the inclusion of the creatinine variable in the analysis made it difficult to discern whether the impact on the LAS was based on both bilirubin and creatinine, or just bilirubin. Given this concern, the Lung Subcommittee requested the SRTR analyze whether the impact of bilirubin on the waitlist component of the LAS was due to bilirubin and creatinine, or bilirubin alone.

The Lung Subcommittee reviewed this SRTR analysis in late October 2008 and again at its November 20, 2008 meeting. Based on this analysis, the Lung Subcommittee made the following policy recommendations to the Committee:

- Add a current bilirubin value that is at least 1.0 mg/dL to the LAS for all diagnosis groups; and
- Add change (increase) in bilirubin that is at least 50% to the LAS for diagnosis Group B, provided that the highest value used in the change calculation is at least 1.0 mg/dL and the change occurs in a six-month period.

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<sup>1</sup>The Committee's earlier deliberations on this topic are recorded in the February 20-21, 2008 and November 17-18, 2008 reports submitted to the Board of Directors.

<sup>2</sup>To review this change in bilirubin public comment proposal, please visit the following web site and click on the first pdf document to the right of the title, "Thoracic Organ Transplantation Committee - Proposal to add the factor 'change in bilirubin' to the lung allocation score (LAS) Policy affected: 3.7.6.1 - (Candidates Age 12 and Older):" <http://www.optn.org/policiesAndBylaws/publicComment/proposals.asp>.

<sup>3</sup>The initial statistical model that included bilirubin also analyzed the addition of "current" and "change in creatinine" in the lung allocation score. Both creatinine factors were statistically significant. However, the Committee sought additional analyses and will discuss again the inclusion of current and change in creatinine in the waiting list component of the LAS. The current LAS calculation does include creatinine, but only in the pos-transplant component.

At its meeting on November 21, 2008, the Committee supported this revised bilirubin policy proposal and voted in favor of submitting this new proposal for public comment (22-Yes, 0-No, 0-Abstention).

The Committee distributed this proposal for public comment during the February 6, 2009 through April 24, 2009 cycle. The Committee received favorable feedback on the proposal. The briefing paper includes this feedback, the Committee's responses to the comments received, as well as the argument for adding current bilirubin and change in bilirubin to the LAS (see Exhibit A – *not in CD; will be in Board Book*). Based on the feedback received, the Lung Subcommittee recommended (through electronic communications) that the Thoracic Committee forward the bilirubin policy proposal to the Board of Directors for review: 10-Yes; 0-No; 0-Abstention<sup>4</sup>. The Committee voted electronically (21-Yes, 0-No, 0-Abstention)<sup>5</sup> to submit the following resolution and proposed policy language for consideration by the Board of Directors:

**\*\*RESOLVED, that Policy 3.7.6.1 (Candidates Age 12 and Older) shall be modified as set forth below, effective pending programming (see Exhibit B) and notice to the membership:**

**3.7.6.1 Candidates Age 12 and Older.** Candidates age 12 and older are assigned priority for lung offers based upon Lung Allocation Score, which is calculated using the following measures: (i) waitlist urgency measure (expected number of days lived without a transplant during an additional year on the waitlist), (ii) post-transplant survival measure (expected number of days lived during the first year post-transplant), and (iii) transplant benefit measure (post-transplant survival measure minus waitlist urgency measure). Waitlist urgency measure and post-transplant survival measure (used in the calculation of transplant benefit measure) are developed using Cox proportional hazards models. Factors determined to be important predictors of waitlist mortality and post-transplant survival are listed below in Tables 1 and 2. It is expected that these factors will change over time as new data are available and added to the models. The Thoracic Organ Transplantation Committee will review these data in regular intervals of approximately six months and will propose changes to Tables 1 and 2 as appropriate.

**Table 1  
Factors Used to Predict Risk of Death on the Lung Transplant Waitlist**

1.	Forced vital capacity (FVC)
2.	Pulmonary artery (PA) systolic <u>pressure</u> (Groups A, C, and D – see 3.7.6.1.a)
3.	O <sub>2</sub> required at rest (Groups A, C, and D – see 3.7.6.1.a)
4.	Age
5.	Body mass index (BMI)
6.	Diabetes
7.	Functional status
8.	Six-minute walk distance
9.	Continuous mechanical ventilation
10.	Diagnosis
11.	PCO <sub>2</sub> (see 3.7.6.1.b)
12.	<u>Bilirubin (current bilirubin – all groups; change in bilirubin – Group B; see 3.7.6.1.c)</u>

[No further changes are proposed to this section of Policy 3.7.6.1.]

<sup>4</sup>Two Subcommittee members did not respond to the query for votes.

<sup>5</sup>The remaining six voting members on the Committee did not respond to this query.

a. Lung Disease Diagnosis Groups

[No changes are proposed to this section of Policy 3.7.6.1.]

b. PCO<sub>2</sub> in the Lung Allocation Score

[No changes are proposed to this section of Policy 3.7.6.1.]

c. Bilirubin in the Lung Allocation Score

UNet<sup>SM</sup> will use two measures of total bilirubin in a candidate's lung allocation score calculation: current bilirubin (for all candidates), and change in bilirubin (for Group B only). There are two types of bilirubin change calculations: "threshold change" and "threshold change maintenance." This section of Policy 3.7.6.1 explains how UNet<sup>SM</sup> uses bilirubin in the lung allocation score.

(i) Definition of Current Bilirubin

Current bilirubin is the total bilirubin value with the most recent test date and time entered in UNet<sup>SM</sup>. UNet<sup>SM</sup> will include in the lung allocation score calculation a current bilirubin value that is at least 1.0 mg/dL.

(ii) Expiration of Current Bilirubin Value

UNet<sup>SM</sup> will evaluate a current bilirubin value as expired according to Policy 3.7.6.3.2.

(iii) Use of Normal Clinical Value for Current Bilirubin

The normal clinical value of current bilirubin is 0.7 mg/dL. UNet<sup>SM</sup> will substitute this normal clinical value in the lung allocation score calculation when the value of current bilirubin is less than 0.7 mg/dL, missing, or expired.

(iv) Bilirubin Values Used in the Change Calculations (Group B Only)

There are two types of bilirubin change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the bilirubin change is 50% or higher. In this calculation, UNet<sup>SM</sup> will use highest and lowest values of bilirubin. The test date of the lowest value must be earlier than the test date of the highest value. The highest value must be at least 1.0 mg/dL. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet<sup>SM</sup> will use an expired lowest value, but not an expired highest value. If a value is less than 0.7 mg/dL, UNet<sup>SM</sup> will substitute the normal clinical value of 0.7 mg/dL before calculating change. The equation for threshold change is [(highest bilirubin – lowest bilirubin)/lowest bilirubin].

The threshold change maintenance calculation occurs *after* the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current bilirubin value must be at least 50% higher than the lowest value used in the threshold change calculation. The equation for threshold change maintenance is [(current bilirubin – lowest bilirubin)/lowest bilirubin].

UNet<sup>SM</sup> will perform the threshold change maintenance calculation either when the current bilirubin value expires (Policy 3.7.6.3.2) or a new current bilirubin value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current bilirubin value can be the highest one that was used in the threshold change calculation. If a current bilirubin value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current bilirubin value expires, UNet<sup>SM</sup> will substitute that expired value with the normal clinical value of 0.7 mg/dL. This normal value, therefore, cannot be 50% higher than the lowest value in the threshold change calculation.

If a center enters a new current bilirubin value for a candidate who has lost the impact from threshold change, UNet<sup>SM</sup> will perform the threshold change maintenance calculation. If the new current bilirubin value is at least 50% higher than the lowest value used in the threshold change calculation, UNet<sup>SM</sup> will reapply the impact from threshold change to the candidate's lung allocation score.

(v) *Impact of Bilirubin Threshold Change in the Lung Allocation Score (Group B only)*

A change in bilirubin that is 50% or higher, or threshold change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current bilirubin is at least 50% higher than the lowest value used in the threshold change calculation.

**\*\*There are no further changes to Policy 3.7.6.1.\*\***

## **2. Addition and Reclassification of Lung Diagnoses**

On February 25, 2009, UNOS staff discussed with the Lung Subcommittee a historical programming request from the Committee: addition of the re-transplant codes "Re-Tx/GF Obliterative Bronchiolitis-Restrictive" and "Lung Re-TX/FG Obliterative Bronchiolitis-Obstructive." The Subcommittee discussed this request and recommended that these two codes be added to the diagnosis field for candidates who are 12 years of age or older.

The Subcommittee also considered the medical currency of the list of diagnoses (**Exhibit C**). The Subcommittee queried whether all of the diagnoses in the list were being selected (i.e., used), and what diagnoses were entered in the "other" category. UNOS staff reported that centers selected all diagnoses, but with varying frequency. UNOS staff reported that the most frequent diagnosis reported in the "other" category is usual interstitial pneumonitis (UIP). The Subcommittee commented that the majority of idiopathic pulmonary fibrosis (IPF) is UIP. Since centers are entering UIP in the "other" field, the Subcommittee recommended that UNOS add UIP as an item in the lung diagnosis list. The Subcommittee discussed a combined IPF/UIP item, but decided that quantifiable data entry may be better achieved if IPF and UIP were two separate items in the diagnosis field. The Subcommittee recommended the addition of UIP and that this diagnosis be classified the same as IPF (Group D).

The Subcommittee also commented that constrictive bronchiolitis and obliterative bronchiolitis (not re-transplant) are the same disease. UNet<sup>SM</sup> classifies the latter as Group D, but the former as Group A. The Subcommittee suggested re-classification of "constrictive bronchiolitis" as Diagnosis Group D, not A.

At its March 27, 2009 meeting, the Committee voted in favor (16-Yes; 0-No; 0-Abstentions) of the Lung Subcommittee's programming recommendations. The Committee asks the Board to consider the following recommendation:

**\*\*RESOLVED, that programming to modify the lung diagnosis data element, as set forth in Exhibit D, is hereby approved, effective pending programming in UNet<sup>SM</sup>.**

### 3. Changes to the Heart Status Justification Forms: Inotrope Dosage and Types

At its November 21, 2008 meeting, the Committee deliberated on queries posed by the UNOS Department of Evaluation and Quality regarding UNet<sup>SM</sup> programming of inotrope data elements (see **Exhibit E**). Per Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status), a heart transplant candidate who receives a single, high-dose inotrope or combination of inotropes qualifies as either Status 1A or Status 1B. (Examples of inotropes are dobutamine, milrinone, and dopamine.)

As described in **Exhibit E**, UNet<sup>SM</sup> currently allows for the entry of only one number to the right of the decimal point for an inotrope dosage. If a user enters more than one number to the right of the decimal, UNet<sup>SM</sup> does not round the value entered. Rather, UNet<sup>SM</sup> truncates the dosage amount to one number to the right of the decimal point. This dosage truncation poses challenges during an audit of candidate data records at centers as inotrope data in the centers' records may not match those entered in UNet<sup>SM</sup>.

The Committee commented that UNet<sup>SM</sup> should not truncate dosage values, and that the numbers allowed for entry – to the right of the decimal point – should be greater than one. The Committee discussed enabling UNet<sup>SM</sup> to allow for two numbers to the right of the decimal point; and, truncate any remaining numbers entered. However, this truncation would counter the intent for data in UNet<sup>SM</sup> to match data in a candidate's record at his/her center. The Committee also considered enabling UNet<sup>SM</sup> to collect however many numbers a center enters for an inotrope dosage. Programming UNet<sup>SM</sup> to collect these extra numbers is relatively straightforward, but will require approval by the OPTN/UNOS Board of Directors. The Committee tasked the Heart Subcommittee to further discuss this topic, and present recommendations at the March 27, 2009 meeting.

The Heart Subcommittee met on February 13, 2009 to discuss truncation of inotrope dosage values. After some discussion that occurred in conjunction with a conversation about inotrope types acceptable in combinations or alone (i.e., single, high-dose), the Subcommittee recommended that UNet<sup>SM</sup> should allow centers to enter three numbers to the right of the decimal point. The Subcommittee's clinical expertise served as evidence for inotrope dosage amounts typically prescribed.

On March 27, 2009, the Heart Subcommittee presented its recommendations to the Committee. The Committee voted in favor of this Subcommittee's programming recommendation (16-Yes; 0-No; 0-Abstention):

**\*\*RESOLVED, that allowing centers to enter up to three numbers to the right of the decimal point for an inotrope dosage, as set forth in Exhibit F, is hereby approved, effective pending programming in UNet<sup>SM</sup>.**

Types of inotropes currently programmed in UNet<sup>SM</sup> are milrinone, dobutamine, dopamine, epinephrine, norepinephrine, phenylephrine, vasopressin, IV nitroglycerin, nesiritide, and nitroprusside (see **Exhibit E**). The Committee expressed concerns with these medications programmed as inotropes in UNet<sup>SM</sup>. Some of these medications are not inotropes. The Heart Review Board staff commented that when reviewing heart status justification forms submitted due to inotrope administration, it only considers forms that document the following as single, high-dose inotropes: dobutamine  $\geq 7.5$  mcg/kg/min; milrinone  $\geq 0.5$  mcg/kg/min; and, dopamine  $\geq 7.5$  mcg/kg/min. If a center submits an inotrope type that is not one of these three, then the Heart Review Board staff informs the center that the inotrope

medication submitted does not comply with Policy 3.7.3 or 3.7.4, as applicable. Therefore, the programming of inotropes in UNet<sup>SM</sup> is not due to a member policy compliance issue.

The Committee discussed the history of the inotrope programming and could not fathom the rationale for including non-inotropes in the list. Examples of non-inotropes included nesiritide and nitroprusside. To more thoroughly discuss what constitutes an inotrope, the Committee tasked the Heart Subcommittee to further discuss this topic and make programming recommendations.

During its February 13, 2009 meeting, the Heart Subcommittee commented that the following medications were vasoactives, and not inotropes. The Subcommittee considered incorporating vasoactive medications, but noted that to do so would require a change in the policy language. Further, if vasoactive medicines are not inotropes, then they should not be considered as such. To comply with Policies 3.7.3 and 3.7.4, the Subcommittee recommended the following changes to inotrope programming in UNet<sup>SM</sup>:

<b>Column I Acceptable Single, High-Dose Intrope (Compliant with Policies 3.7.3 and 3.7.4)</b>	<b>Column II Acceptable Inotrope Combination</b>	<b>Column III Medication to Delete from UNet<sup>SM</sup></b>
Dobutamine $\geq 7.5$ mcg/kg/min	Dobutamine with any of the four drugs listed in Column I, <i>or</i> Norepinephrine	Phenylephrine
Dopamine $\geq 7.5$ mcg/kg/min	Dopamine with any of the four drugs listed in Column I, <i>or</i> Norepinephrine	Vasopressin
Milrinone $\geq 0.5$ mcg/kg/min	Milrinone with any of the four drugs listed in Column I, <i>or</i> Norepinephrine	IV Nitroglycerin
Epinephrine $\geq 0.02$ mcg/kg/min	Epinephrine with any of the four drugs listed in Column I, <i>or</i> Norepinephrine	Nesiritide
<i>NOTE: All medications listed in this table already exist in UNet<sup>SM</sup>.</i>		Nitroprusside

The Heart Subcommittee presented its recommendations to the Committee on March 27, 2009. The Committee voted in favor of the Subcommittee's recommendations (16-Yes; 0-No; 0-Abstention). The Committee asks the Board to consider the following recommendations:

**\*\*RESOLVED, that programming that limits single, high-dose inotropes to include only dobutamine ( $\geq 7.5$  mcg/kg/min), dopamine ( $\geq 7.5$  mcg/kg/min), milrinone ( $\geq 0.5$  mcg/kg/min), and epinephrine ( $\geq 0.02$  mcg/kg/min), as set forth in Exhibit F, is hereby approved, effective pending programming in UNet<sup>SM</sup>.**

**\*\*FURTHER RESOLVED, that programming that limits combinations of inotropes to include dobutamine, dopamine, milrinone, epinephrine, and norepinephrine, as set forth in Exhibit F, is hereby approved, effective pending programming in UNet<sup>SM</sup>.**

<b>Thoracic Organ Transplantation Committee</b>	<b>November 21, 2008 Chicago, Illinois</b>	
<b>Name</b>	<b>Position</b>	<b>Attendance</b>
Maryl R. Johnson, MD	Chair	X
Mark L. Barr, MD	Vice Chair	X
J. David Vega, MD	Ex Officio	X
David DeNofrio, MD	Regional Rep. (1)	X
Kenneth R. McCurry, MD	Regional Rep. (2)	X
Mark Rolfe, MD	Regional Rep. (3)	X
Luis F. Angel, MD	Regional Rep. (4)	X
John Chin, MD	Regional Rep. (5)	
Howard Song, MD	Regional Rep. (6)	X
Robert B. Love, MD	Regional Rep. (7)	
A. Michael Borkon, MD	Regional Rep. (8)	X
Sean P. Pinney, MD	Regional Rep. (9)	X
Kevin M. Chan, MD	Regional Rep. (10)	X
Isabel P. Neuringer, MD	Regional Rep. (11)	X
Bruce W. Brooks	At Large	By phone
Gregory S. Couper, MD	At Large	X
R. Duane Davis, MD	At Large	X
William Fiser, MD	At Large	By phone
Edward Garrity, Jr., MD, MBA	At Large	X
Herbert Heili	At Large	
Diane Lynn Kasper, RN, CCTC	At Large	X
Denise Kinder, RN, CPTC	At Large	
David P. Nelson, MD	At Large	X
Genevieve Reilly, NP	At Large	X
Stuart Sweet, MD, PhD	At Large	X
Elbert P. Trulock III, MD	At Large	X
Steven A. Webber, MBChb	At Large	X
Amy Shorin-Silverstein, JD	BOD - Liaison	By phone
Monica Lin, PhD	Ex Officio – HRSA	X
Bernard Kozlovsky, MD	SRTR Liaison	By phone
Brad Dyke, MD	SRTR Liaison	X
Robert M. Merion, MD	SRTR Liaison	
Jeff Moore MS	SRTR Liaison	X
Susan Murray, ScD	SRTR Liaison	X
Tiffani Pace	SRTR Liaison	
Katherine Pearson	SRTR Liaison	
Tempie Shearon	SRTR Liaison	
Leah Edwards, PhD	Support Staff	X
Vipra Ghimire, MPH, CHES	Committee Liaison	X
Karl McCleary, PhD, MPH	Support Staff	X
Aaron Powell	Support Staff	X
Mary D. Ellison, PhD	Support Staff	By phone
Catherine Monstello	Support Staff	By phone
Aaron McKoy	Support Staff	By phone
Donna Whelan	Support Staff	By phone

<b>Thoracic Organ Transplantation Committee</b>		<b>March 27, 2009 Chicago, Illinois</b>	
<b>Name</b>	<b>Position</b>	<b>Attendance</b>	
Maryl R. Johnson, MD	Chair	X	
Mark L. Barr, MD	Vice Chair	X	
J. David Vega, MD	Ex Officio	X	
David DeNofrio, MD	Regional Rep. (1)	X	
Raymond Benza, MD	Regional Rep. (2)	By phone	
Mark Rolfe, MD	Regional Rep. (3)	By phone	
Luis F. Angel, MD	Regional Rep. (4)	X	
John Chin, MD	Regional Rep. (5)		
Howard Song, MD	Regional Rep. (6)		
Robert B. Love, MD	Regional Rep. (7)		
A. Michael Borkon, MD	Regional Rep. (8)	X	
Sean P. Pinney, MD	Regional Rep. (9)	X	
Kevin M. Chan, MD	Regional Rep. (10)		
Isabel P. Neuringer, MD	Regional Rep. (11)		
Bruce W. Brooks	At Large		
Gregory S. Couper, MD	At Large	X	
R. Duane Davis, MD	At Large	X	
William Fiser, MD	At Large	X	
Edward Garrity, Jr., MD, MBA	At Large		
Herbert Heili	At Large		
Diane Lynn Kasper, RN, CCTC	At Large	X	
Denise Kinder, RN, CPTC	At Large	X	
David P. Nelson, MD	At Large		
Genevieve Reilly, NP	At Large	X	
Stuart Sweet, MD, PhD	At Large	X	
Elbert P. Trulock III, MD	At Large		
Steven A. Webber, MBChb	At Large	X	
Amy Shorin-Silverstein, JD	BOD - Liaison		
Monica Lin, PhD	Ex Officio – HRSA	X	
Bernard Kozlovsky, MD	SRTR Liaison	By phone	
Brad Dyke, MD	SRTR Liaison	X	
Susan Murray, ScD	SRTR Liaison	X	
Tempie Shearon	SRTR Liaison	X	
Jeff Moore MS	SRTR Liaison		
Nadirah Pitts	SRTR Liaison		
Katherine Pearson	SRTR Liaison		
Robert M. Merion, MD	SRTR Liaison		
Leah Edwards, PhD	Support Staff	X	
Vipra Ghimire, MPH, CHES	Committee Liaison	X	
Aaron McKoy	Support Staff	By phone	
Nell Aronoff	Support Staff	By phone	
Jory Parker	Support Staff	By phone	
Aaron Powell	Support Staff	By phone	
Betsy Colburn	Support Staff	By phone	
Donna Whelan	Support Staff	By phone	
Alex Miller	Support Staff	By phone	